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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,658	05/24/2002	Hugh A. Sampson	2002834-0069	1354

7590 08/05/2004

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	09/989,658	SAMPSON ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *9-12, 37a* is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 9-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 9 recites "the kit of claim 6", claim 6 is not drawn to a kit. Applicant is required to amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The numbering of claims (starting from claim 37a) is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 37a-47 have been renumbered as claims 38-48.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-32 are drawn to a non-human animal characterized in that when presented with a potential sensitizing antigen in combination with cholera toxin, the animal develops an anaphylaxis reaction. Classified in class 800, subclass 8.

II. Claims 6 and 7 are drawn to a non-human animal characterized in that when presented with a potential sensitizing antigen in combination with cholera toxin, the animal does not develop an anaphylaxis reaction. Classified in class 800, subclass 8.

III. Claims 33-41 are drawn to a method for using a sensitized animal to detect or assess an allergen. Classified in class 424, subclass 9.1.

IV. Claims 42-48 are drawn to a method of sensitizing an animal. Classified in class 424, subclass 184.1.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II and I are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group I is drawn to a non-human animal characterized in that when presented with a potential sensitizing antigen in combination with cholera toxin, the animal develops an anaphylaxis reaction, whereas group II is drawn to a non-human animal characterized in that when presented with a potential sensitizing antigen in combination with cholera toxin, the animal does not develop an anaphylaxis reaction. The animals of group II and I are distinct and mutually exclusive as far as the anaphylaxis reaction is concerned.

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, group I is drawn to a non-human animal that has an allergic response to an antigen, such as an irritated GI tract allergic response to an orally-delivered antigen; group II is drawn to using an antigen-sensitized non-human animal for assessing the presence of an antigen in a test substance. The sensitized animal of group I could be used in a materially different method, for example for testing the efficacy of an anti-allergy medication, and the presence of antigens could be assessed with materially different products, such as a non-human animal having asthma to an intranasally-delivered antigen, or a non-human animal having a systemic allergic response to an intravenously-delivered antigen.

Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the non-human animal could be made without the pre-existing GI tract inflammation, and the process as claimed can be used to make different type of non-human animals having different allergic responses depending on the type of non-human animals used, sensitizing composition used, the route of allergen administration, and the presence or absence of an adjuvant such as cholera toxin.

The differences of the Inventions I-IV are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

It is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process

Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention I is directed to a non-human animal having an allergic response, which encompasses a multitude of patentably distinct species of the claimed invention - a multitude of specific non-human animals, wherein each species is defined by the combination of the following elements: a). The type of a non-human animal selected from a group consisting of rat, mouse, rabbit, ferret, hamster, guinea pig, baboon, monkeys, gorillas, apes, and orangutans; b). The type of antigens selected from the group consisting of a food antigen such as one of those recited in claim 24, an environmental antigen such as one of those recited in claim 28, or a pharmaceutical agent; c). The type of allergic response triggered, such as intestinal, respiratory, and

systemic anaphylaxis; e). The presence or absence of a GI tract inflammation prior to the administration of allergen; g) the type of non-allergens that the animal would not respond to (if applicable). If invention group I is elected, further election of a species comprising each of the five elements as indicated is necessary.

Invention III is directed to using a non-human animal having an allergic response for testing. If invention III is elected, further election of a species drawn to a particular species of a non-human animal is necessary, wherein the species is defined by the characteristics of above elements a)-g) is necessary.

Invention IV is directed to a method of sensitizing a non-human animal, which encompasses multitude means of sensitization, wherein each species is defined by the combination of the following elements: a). The type of a non-human animal selected from a group consisting of rat, mouse, rabbit, ferret, hamster, guinea pig, baboon, monkeys, gorillas, apes, and orangutans; b). The type of agent causative for the inflamed gastrointestinal tract selected from the group consisting of a virus, bacteria, and a chemical, c) the type of antigens selected from the group consisting of a food antigen such as one of those recited in claim 24, an environmental antigen such as one of those recited in claim 28, and a pharmaceutical agent; d). the route of administration of the antigens; e). the type of allergic response triggered; f). the presence or absence of an adjuvant such as cholera toxin; g). The type of non-allergens that the animal would not respond to (if applicable). If invention IV is elected, further election of a species comprising each of the seven elements as indicated is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic, i.e. no single claim is directed to a specific species as defined above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

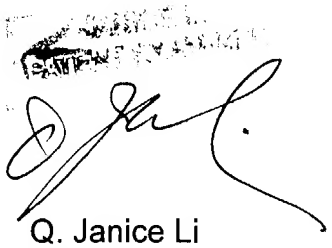
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist **Rena Jones** whose telephone number is **571-272-0571**.



Q. Janice Li
Patent Examiner
Art Unit 1632

QL
July 23, 2004